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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/933,780 | 08/21/2001 | Yong Guo | HMR2053 USNP1 | 6740 |

5487 7590 06/02/2004
ROSS J. OEHLER
AVENTIS PHARMACEUTICALS INC.
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EXAMINER

DESAI, ANAND U

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/933,780 | GUO ET AL. | |
| | Examiner | Art Unit | |
| | Anand U Desai, Ph.D. | 1653 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/26/02 & 7/18/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, drawn to claims 1-10, and 18-21 in Paper filed on April 23, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL. Claims 11-17 are withdrawn from further consideration as being drawn to non-elected inventions. Claims 1-10, and 18-21 are currently pending and are under examination.

Priority

2. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(e). The priority date is August 25, 2000.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on February 26, 2002, and July 18, 2003 are being considered by the examiner.

Specification

4. The disclosure is objected to because of the following informalities:

There appears to be typographical errors; On page 9, line 5; There is a "1" next to the abbreviation for "(NLSs)1"? On page 12, line 19, the degree symbol is missing for "4 °C". The abbreviation, "NTS" on page 9, line 27 has not been initially spelled out for the first identification. Is it a nuclear translocation signal or a nuclear transport sequence?

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6, 10, and 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. In claim 18, what is the second component that makes up a fusion protein? Description of the compound of interest is not complete. Claims 19-21 are rejected for depending on rejected claim 18.

8. Claim 6 recites the limitation "the mammalian Period protein" in first line. There is insufficient antecedent basis for this limitation in the claim. Suggest "the human Period protein".

9. In claim 10, how are a peptide, protein, and a nucleic acid not a chemical entity?

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 10 is drawn to "any modified form thereof" a peptide, protein, chemical entity, and nucleic acid. To satisfy the written description requirement, the specification must describe the

Art Unit: 1653

invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. The specification does not clearly describe the “modified forms thereof” that could be used as a compound of interest.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-3, 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Nakanishi et al. U.S. Patent 6,235,521 (Effective filing date=September 10, 1999). Nakanishi et al. disclose a phage head fusion protein that contains a nuclear localization signal. The nuclear localization signal was from the nuclear protein, SV40 large T antigen, and the phage head protein was gpD (see Example 1, and claim 3, current application, claims 1-3, and 10). The SV40-gpD fusion protein comprises the amino acid sequence Arg-His-Lys-His (current application, claim 7, 18). The SV40-gpD fusion protein is made by recombinant DNA technology. The SV40-gpD fusion protein comprises a sequence, Pro-Lys-Lys-Lys-Arg-Lys-Val-spacer- (see U.S. Patent ‘521, Column 7, Example 2, and Table 2, current application, claims 18-21). Thus the fusion protein comprises a sequence, $-(X-X-X-X)_n-$, where n is 1 and each X is selected from arginine, histidine, or lysine, wherein the fusion protein can have an amino acid linker attached between

Art Unit: 1653

the nuclear localization signal and the compound of interest (see U.S. Patent '521, Column 7, lines 45-60, Table 2, current application, claims 1-3, 7-10, and 18-21).

14. Claims 1-3, 7-10, and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Guarente et al. (Molecular and Cellular Biology, pp. 578-585, Vol. 7, No. 2, (1987)). Guarente et al. disclose a yeast fusion protein that comprises a nuclear localization signal, derived from a transcription factor. Guarente et al. disclose a *Saccharomyces cerevisia* HAP2 fusion protein. The HAP2 protein is a transcription factor because it is capable of activating the yeast CYC1 gene through activation of the upstream activator site, *UAS2* (see first paragraph of Discussion section, page 584). The *lexA*-HAP2 fusion protein comprises the amino acid sequence Arg-His-Lys-His. The *lexA*-HAP2 fusion protein is made by recombinant DNA technology (see Material and Methods, page 580, Construction of *lexA*-HAP2 fusion protein, current application, claim 21). Therefore the *lexA*-HAP2 fusion protein comprises a sequence $-(X-X-X-X)_n-$, where n is 1 and each X is selected from arginine, histidine, or lysine (see Figure 3, page 581, the line with nucleotide 810 labelled, current application, claims 1-3, 7-10, and 18-21).

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

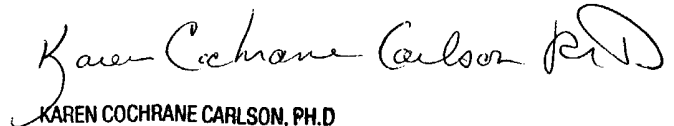
Art Unit: 1653

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (517) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 1, 2004

A handwritten signature, likely of the examiner, consisting of stylized initials and a surname.


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER